K061907

MAR 2 7 2008

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5™ Entropy Module, E-ENTROPY and accessories

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

March 27, 2008

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5™ Entropy Module, E-ENTROPY and accessories

COMMON NAME:

Electroencephalograph

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

Product Code	Classification Name	CFR Section
OLW, OMC, ORT	Electroencephalograph	882.1400

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda S/5™ Entropy Module, E-ENTROPY is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda E- ENTROPY Module (K050835).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The purpose of this submission is to add new marketing claims to the Entropy module, without changing anything in the module's hardware, software or accessories. Scientific justifications for the proposed modifications to the indications for use are provided. The updated indications of use of the module shall be expanded to cover pediatric patients 2 years or older.

Furthermore, we propose to add new claims in adult. Response Entropy (RE) and State Entropy (SE) may be used as an aid in monitoring the effects of certain anesthetic agents, which may help the user to titrate anesthetic drugs according to the individual needs of adult patients. Furthermore in adults, the use of Entropy parameters may help the user to reduce the amount of certain hypnotic drugs and enable faster emergence from anesthesia.

The Entropy Module, E-ENTROPY, is a single-width plug-in parameter module for Datex-Ohmeda modular perioperative monitors, the S/5 AM and S/5 CAM. The parameter and customer specifications or the compatibility with Datex-Ohmeda S/5 monitoring products are not affected by the updated indications for use.

E-ENTROPY is a module used to calculate parameters from electroencephalograph (EEG) and frontal electromyograph (FEMG) signals. The E-ENTROPY module provides two spectral entropy parameters State Entropy (SE) and Response Entropy (RE).

The E-ENTROPY module uses the identical Entropy algorithm and accessories as the predicate device, E-ENTROPY (K050835). Entropy monitoring is based on acquisition of raw EEG and FEMG signals and processing them by using the Entropy algorithm - a Datex-Ohmeda application of spectral entropy based on information theory.

Calculated parameters are:

- Response Entropy, RE (range 0-100), continuous processed variable for fast detection of activation of facial muscles, i.e. FEMG.
- State Entropy, SE (range 0-91), continuous processed variable calculated from the EEG. SE is designed to be sensitive to the hypnotic effect of anesthetic drugs in the brain.
- Burst Suppression Ratio, BSR (range 0-100%), the percentage of epochs in the past 60 seconds in which the EEG signal is considered suppressed.

All the calculated parameters can be selected on the display, and trended. The waveform size, color and sweep speed can be adjusted. Alarms for Entropy are taken care of by the host monitor and follow the user interface for alarms in Datex-Ohmeda S/5 patient monitors. There are auditory and visual alarms and user adjustable limits for Entropy variables. The default is OFF, because the device is not to be used as the sole basis for treatment or therapy but rather as an adjunct to other parameters.

The accessories are the same for the E-ENTROPY module and the predicate device, the E-ENTROPY (K050835).

INTENDED USE as required by 807.92(a)(5)

Intended Use:
The Datex-Ohmeda Entropy module , E-ENTROPY and accessories are intended to be used with Datex-Ohmeda modular multiparameter monitors for monitoring the neurophysiological status of hospitalized patients.

Indications for use:

The Datex-Ohmeda Entropy Module, E-Entropy and accessories are indicated for adult and pediatric patients older than 2 years within a hospital for monitoring the state of the brain by data acquisition of electroencephalograph (EEG) and frontal electromyograph (FEMG) signals. The spectral entropies, Response Entropy (RE) and State Entropy (SE), are processed EEG and FEMG variables. The Entropy measurement is to be used as an adjunct to other physiological parameters.

In adult patients, Response Entropy (RE) and State Entropy (SE) may be used as an aid in monitoring the effects of certain anesthetic agents, which may help the user titrate anesthetic drugs according to the individual needs of adult patients. Furthermore in adults, the use of Entropy parameters may be associated with a reduction of anesthetic use and faster emergence from anesthesia.

The Entropy module is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda S/5™ Entropy Module, E-ENTROPY is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda E- ENTROPY Module (K050835). The only difference between the new E- ENTROPY and the predicate E-ENTROPY (K050835) is the updated indications for use of the Datex-Ohmeda S/5™ E-ENTROPY Module and accessories. The same module with accessories is used as the predicate device (K050835). The purpose is to add new marketing claims to the Entropy module, without changing anything in the module's hardware, software or accessories. Currently, the Datex-Ohmeda S/5™ E-ENTROPY Module (K050835) is intended for use with Datex-Ohmeda modular multiparameter monitors for monitoring the neurophysiological status of hospitalized patients. RE and SE parameters can be used as an aid in monitoring the effects of certain anesthetic agents.
The purpose of this submission is to add new marketing claims to the Entropy module, without changing anything in the module's hardware, software or accessories. Scientific justifications for the proposed modifications to the indications for use are provided. The updated indications of use of the module shall be expanded to cover pediatric patients 2 years or older. Furthermore, we propose to add new claims in adult. Response Entropy (RE) and State Entropy (SE) may be used as an aid in monitoring the effects of certain anesthetic agents, which may help the user to titrate anesthetic drugs according to the individual needs of adult patients. Furthermore in adults, the use of Entropy parameters may help the user to reduce the amount of certain hypnotic drugs and enable faster emergence from anesthesia. The updated indications for use are based on independent, peer-reviewed and published scientific articles in medical journals, as well as studies made internally at GE Healthcare. Based on the analysis and other documentation included in this 510(k) notification and attachments it is evident that the Datex-Ohmeda S/5™ Entropy Module, E-ENTROPY are substantially equivalent to the predicate Datex-Ohmeda E-ENTROPY Module (K050835).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Entropy module E-ENTROPY and accessories are used in a Datex-Ohmeda S/5 monitoring system. The E-ENTROPY module is not a life-supporting device.
The Datex-Ohmeda Entropy module, E-ENTROPY, and accessories have taken into account general electrical safety requirements in the design. The hardware and software and accessories for the E-Entropy module and accessories with extended indications are identical to the predicate E-Entropy module and accessories (K050835). (The details of compliance can be found in the predicate 510(k) submission (K050835) or on file at GE Healthcare Finland Oy).

The following safety standards have been followed:

- COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices
- FDA/DCRND Reviewer Guidance for Premarket Notification Submissions, November 1993
- IEC 60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995 (Part 1: General requirements for safety)
- EN 60601-1:1990 + A1:1993 + A13:1996 + A2:1995 (identical to IEC60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995)
- CAN/CSA C22.2 No. 601.1-M90 + S1:1994 (Canadian deviations to IEC 60601-1:1988 + Amdt. 1:1991) + S2:1998 (+IEC Amdt 2:1995)
- UL 2601-1, October 24, 1997 (U.S. deviations to IEC 60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995)
- IEC 60601-1-2:2001 (Electromagnetic compatibility – Requirements and tests)
- AAMI ES1-1993 (Safe current limits for electromedical apparatus)
- Electroencephalograph Devices Guidance for 510(k) Content, Draft Document Version 1.0 November 3, 1997
- FDA/ODE Guidance for Content of Premarket Submission for Software Contained in Medical Devices. Version 1.0. (May, 29, 1998)
- IEC 60601-2-26 Medical electrical equipment. Part 2: Particular requirements for the safety of electroencephalographs, 2002.
- ISO 14971 Ed. 1: Medical devices - Application of risk management to medical devices
- FDA Performance standard, 21 CFR Part 898.12 - PERFORMANCE STANDARD FOR ELECTRODE LEAD WIRES AND PATIENT CABLES

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5™ Entropy Module, E-ENTROPY and accessories compared to the legally marketed (predicate) Datex-Ohmeda S/5™ Entropy Module, E-ENTROPY and accessories (K050835).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
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GE Healthcare
c/o Mr. Joel Kent
86 Pilgrim Road
Needham, MA 02492

APR - 9 2012

Re: K061907
Trade/Device Name: Datex-Ohmeda S/5™ Entropy Module,
E-ENTROPY and accessories
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLW, OMC, ORT
Dated (Date on orig SE ltr): December 27, 2007
Received (Date on orig SE ltr): December 28, 2007

Dear Mr. Kent:

This letter corrects our substantially equivalent letter of March 27, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ____ K061907_____

Device Name: **Datex-Ohmeda S/5 Entropy Module, E-Entropy and Accessories.**

Indications for Use:

The Datex-Ohmeda Entropy Module, E-Entropy and accessories are indicated for adult and pediatric patients older than 2 years within a hospital for monitoring the state of the brain by data acquisition of electroencephalograph (EEG) and frontal electromyograph (FEMG) signals. The spectral entropies, Response Entropy (RE) and State Entropy (SE), are processed EEG and FEMG variables. The Entropy measurement is to be used as an adjunct to other physiological parameters.

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The Entropy module is indicated for use by qualified medical personnel only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K061907